REMARKS

Corrected filing receipt

Applicants request a corrected filing receipt on separate paper and submit or request charging of the appropriate fee. The present application is a 371 of PCT/EP98/08382, **12/18/98** not 1/15/98.

Specification

The examiner objected to the abstract because it has two paragraphs. Applicants herein submit a replacement abstract on separate page which contains one paragraph.

Applicants amend the specification at lines 30-31 on page 3, to read: "The amino-sequence derived from SEQ ID NO: 1 is to be seen in SEQ ID NO: **2**."

Claim objections

Applicants amend claim 12 as the examiner suggested.

35 USC § 112, first paragraph

The examiner rejected claims 1-17 for lack of written description as the examiner found applicants' arguments (submitted on February 25, 2002) not persuasive.

Since applicants amended claim 1 in the submission made on February 25, 2002 to delete homologs from claim 1 the rejection should only apply to new claims 16 and 17 which are directed to the homologs.

First, applicants remind the examiner that there is a strong presumption that an adequate written description of the claimed invention is present when the application is

filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).

The examiner maintains that for proper written description specific structure-function teachings are necessary. The examiner insists that the disclosure must teach where such deletions, or insertions, or substitutions may be made in the sequence and have the polypeptide retain function to claimed sequences with at least 80% homology with SEQ ID NO: 1.

Applicants respond by pointing out that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d at 1563, 19 USPQ2d at 1116. Applicants believe one of ordinary skill in the art knows that sequences such as the claimed sequences easily can be modified by genetic engineering without affecting the activity of the corresponding protein.

Also, the examiner quotes MPEP § 2163 IA, "a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between the function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." Applicants agree that if an applicant describes a nucleic acid **solely** by its function (e.g., "a cDNA encoding human interleukin-35") then the written description requirement is not met. In the present case, however, applicants do not describe a nucleic acid solely by its function but have disclosed its structure in

the sequence listing as SEQ ID NO: 1. Therefore, 80% homologs are described, even if partially, by the structure. If the applicant relies upon a disclosure of relevant identifying characteristics, such characteristics can include complete or **partial** structure of the claimed invention. MPEP § 2163.

35 USC § 112, second paragraph

The examiner stated that claim 1 is vague and indefinite in reciting "isolated from microorganisms." The phrase encompasses both isolation from a single microorganism or a plurality of microorganisms.

The examiner believes there is insufficient antecedent basis "the organisms" in line 6 of claim 9. To overcome the rejection applicants delete "the" from "the organisms."

Applicants amend claim 10 to remove the redundancy pointed out by the examiner.

The examiner stated that claim 14 is vague and indefinite in lacking a step that clearly relates back to the preamble. Applicants add a step in claim 14 which relates back to the preamble.

Applicants amend claim 15 according to the examiner's suggestion.

The examiner stated that claims 16 and 17 are vague because it is not clear whether these claims are drawn to a composition comprised of homologs or are the claims drawn to a single homolog. "Homologs" here refer to one or more homologs. Applicants believe this meaning should be clear to a person of ordinary skill in the art.

In view of the foregoing amendments and remarks, applicants believe the present application is in condition for allowance. Favorable action therefore is requested.

A check in the amount of $110.00 is attached to cover the required one month extension fee.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Page 3, lines 26-44, should read:

Homologs of the novel orotidine-5'-phosphate decarboxylase gene having the sequence SEQ ID NO: 1 mean, for example, allelic variants which have at least 80% homology at the derived amino-acid level, preferably at least 90% homology, very particularly preferably at least 95% homology. The amino-acid sequence derived from SEQ ID NO: 1 is to be seen in SEQ ID NO: [1] 2. Allelic variants comprise, in particular, functional variants which are obtainable by deletion, insertion or substitution of nucleotides from the sequence depicted in SEQ ID NO: 1, the intention being, however, that the enzymatic activity of the derived synthesized proteins advantageously be retained for the insertion of one or more genes. However, if the intention is to produce mutants in the orotidine-5'-phosphate decarboxylase gene with the aid of SEQ ID NO: 1 and its homologs in the novel process for producing uracil-auxotrophic microorganisms, non-functional genes will be used, that is to say genes which lead to enzymatically inactive proteins. In this case, it is advantageous to use sequences which display [homologies] homologs with SEQ ID NO: 1 or its homologs advantageously at the 3' and 5' ends.

IN THE CLAIMS:

10. (amended) A process for inserting DNA into microorganisms, which comprises inserting a vector which comprises an intact orotidine-5'-phosphate decarboxylase gene having the sequence SEQ ID NO: 1 or its homologs isolated from microorganisms which have at least 80% homology with the sequences

SEQ ID NO: 1 as claimed in claim 1 together with at least one other nucleic acid sequence, into a microorganism which is deficient in orotidine-5'-phosphate decarboxylase nucleic acid sequence having the sequence SEQ ID NO: 1 [or its homologs as claimed in claim 1 together with at least one other nucleic acid sequence, into a microorganism which is deficient in orotidine-5'-phosphate decarboxylase nucleic acid sequences,] and cultivating this microorganism on or in a culture medium without uracil.

12. (amended) A process as claimed in claim 10, wherein an *Ashbya gossypii* strain is used as the microorganism deficient in orotidine-5'-phosphate decarboxylase genes.

14. (amended) A process for selecting cells, said process comprising the step of transforming cells with a gene sequence or its homologs as claimed in claim 1 and selecting for the transformed cells.

15. (amended) The process as claimed in claim 14 [for] wherein said cells are *Ashbya gossypii.*